IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NIPPON SHINYAKU CO., LTD., Plaintiff, v. SAREPTA THERAPEUTICS, INC., Defendant.	C.A. No. 21-1015 (JLH) **DEMAND FOR JURY TRIAL**
SAREPTA THERAPEUTICS, INC. and THE UNIVERSITY OF WESTERN AUSTRALIA, Defendant/Counter-Plaintiffs v. NIPPON SHINYAKU CO., LTD. and NS PHARMA, INC., Plaintiff/Counter Defendants.	[redacted] [redacted]

NS'S OMNIBUS REPLY IN SUPPORT OF ITS MOTIONS FOR SUMMARY JUDGMENT

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I. THE COURT SHOULD GRANT JUDGMENT OF INVALIDITY UNDER SECTION 112

Sarepta opposes the UWA Patents' invalidity, but its own admissions preclude any genuine dispute that (1) the claimed genus encompasses at least many thousands of AO candidates; and (2) the art is highly unpredictable, dooming its arguments. In a misguided attempt to salvage its claims, Sarepta recycles arguments from past overreaching patentees, namely by relying on the "newly characterized antigen" test, "routine" experimentation, and post-priority date evidence. The Federal Circuit has squarely rejected each of these approaches. The Court should therefore grant summary judgment of invalidity under Section 112.

A. The Undisputed Facts Establish that the UWA Patents Claim a Vast Genus of AOs of at Least Hundreds of Thousands

Despite repeatedly characterizing the UWA Patents' claimed genus as "limited," "small" or "narrowly-tailored," (D.I. 469 (Opp'n) at 1-2, 5, 7, 8, 15, n.4), Sarepta never provides the Court with a smaller estimate of candidate AOs than NS's lower bounds of at least hundreds of thousands. Why? Because Sarepta cannot. When viewed in the light most favorable to Sarepta, its claimed genus numbers in at least the hundreds of thousands, and possibly into the trillions. D.I. 400 at 8; D.I. 401 (SOF) ¶ 5. Both NS's expert, Dr. Hastings, and Sarepta's expert, Dr. Dowdy, [redacted] D.I. 401 (SOF) ¶¶ 5-9. These calculations do not "ignore" claim limitations, (D.I. 469 at 15), but conservatively consider "[redacted]" and do "[redacted]" (D.I. 401 (SOF) ¶ 9).

Even Dr. Dowdy's calculations produce sizeable numbers. In his view, [redacted] (D.I.

[1] The Court held that the recited "base sequence" does not necessarily extend the entire length of the AO, and that an AO may have "additional bases." *See* D.I. 248 at 8-11.

401 (SOF) ¶ 6), [redacted] (*id.* ¶¶ 6, 8). [redacted], Dr. Dowdy [redacted] *Id.* ¶ 6. Dr. Dowdy testified that [redacted]. *Id.* [redacted] *Id.* ¶ 9.[2] Thus, even Sarepta's overly conservative estimates based on improper claim construction produce a vast genus. *PureCircle USA Inc. v. SweeGen, Inc.*, No. 2022-1946, 2024 WL 20567, at *3 (Fed. Cir. Jan. 2, 2024) (no written description if only "9,000 possible" candidates); *Idenix Pharms. LLC v. Gilead Scis. Inc.*, 941 F.3d 1149, 1157-58 (Fed. Cir. 2019) (same with "more than 7,000 unique configurations"). Applying the Court's construction, (*see* D.I. 421 at 1-3), NS's "[redacted] stands wholly unrebutted and is even more vast, (D.I. 401 (SOF) ¶ 5). Thus, no reasonable jury could find the claimed genus is "limited" or "narrow."

B. The Undisputed Facts Establish that the Art Was Highly Unpredictable and Required Empirical Testing of Individual AOs

Sarepta also premises its opposition on purported "predictability" in the field. *See* D.I. 469 at 13-15, 19. It agrees the field was highly unpredictable before the UWA Patent's June 2005 filing date, (D.I. 470 (CSOF) ¶ 1.1), but then argues that the art "became predictable" through the work "disclosed" in the UWA Patents, (D.I. 469 at 13, 21-22). Sarepta's admissions belie this argument. [redacted] Dr.

[2] Sarepta implies that functionality narrows the genus. *See* D.I. 469 at 8 and n.4. Under Federal Circuit law, such "analysis is backwards." *Idenix*, 941 F.3d at 1162 (the "disparity" between functional and non-functional candidates "requires significant experimentation, which weighs against enablement, not for it"); *Baxalta Inc. v. Genentech, Inc.*, 579 F. Supp. 3d 595, 617 (D. Del. 2022) (Dyk, J.) (that only some "antibodies will satisfy the claim limitations" "exemplifies how substantial experimentation is necessary to sift through" candidates).

Dowdy [redacted] D.I. 401 (SOF) ¶¶ 6, 14; Ex. 60, (Dowdy Dep.) at 44:4-15. [redacted] D.I. 401 (SOF) ¶ 14; Ex. 60, (Dowdy Dep.) at 44:20-22. Dr. Dowdy also agrees [redacted] (D.I. 401 (SOF) ¶ 8), [redacted] (*id.* ¶ 7 [redacted]). Consequently, the vast majority of AO candidates—those with 1, 2, 3, or 4 mismatched bases—will undisputedly have high functional unpredictability.[3] *See also* D.I. 427-2, Ex. 2 (Dowdy Rebuttal) ¶ 57, tbl. 1 ([redacted]).

Sarepta concedes this point but tries to spin it as evidence of predictability. *See* D.I. 469 at 21-22. This defies logic. That a (small) portion of the genus might be relatively more predictable than the remainder only reinforces the need for representative disclosures showing "possession of the breadth of the genus" and enabling a POSA to "make and use . . . embodiments across the full scope of the claim."[4] *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 967 (Fed. Cir. 2002); *PPG Indus., Inc. v. Guardian Indus. Corp.*, 75 F.3d 1558, 1564 (Fed. Cir. 1996).

Sarepta's new-found assertions of predictability also directly contradict its prior statements to the PTO. *See* D.I. 469 at 13-14, 21. It is immaterial that Sarepta's prosecution statements addressed an obviousness rejection or that the interference sought to invalidate another patent because the nature of the proceedings have no bearing on factual statements made concerning the

[3] [redacted]

[4] Emphasis added throughout unless otherwise indicated.

state of the predictability in exon 53 skipping. D.I. 469 at 14. In Sarepta's own words, in 2018 prosecution of the '851 Patent: "recognition of the lack of predictability in the field of exon skipping continued beyond 2005." D.I. 401 (SOF) ¶ 11 (noting Sarepta's reliance on 2007 and 2011 publications as evidence of a continued lack of "clear rules," continued need for "trial and error procedure," and that "exon skipping remains an unpredictable exercise"). Sarepta likewise stated in 2014 that "[e]xon skipping of dystrophin pre-mRNA was a nascent and highly unpredictable technology . . . and remains so today[]." D.I. 427-23, Ex. 23 (UWA Mot. 1) at 17; *see also* D.I. 401 (SOF) ¶¶ 12-13 (Sarepta describing "tremendous variability and unpredictability" and that "operative sequences are actually highly unpredictable" based on its "subsequent experience" to the UWA Patents). Sarepta should not be permitted to change its position now.

Given Sarepta's and Dr. Dowdy's admissions, a reasonable jury could only find the art was unpredictable and to required testing to determine whether a given AO candidate functioned.

C. The UWA Patents Are Invalid for Lack of Written Description

Sarepta argues (1) for a purported "structure-function correlation" ostensibly provided by a "hot spot," (D.I. 469 at 9-13, 16-17); and (2) that the sole disclosed species is purportedly "representative" of the claimed genus, (*id.* at 17-18). Neither argument has merit.

1. The Specification Does Not Disclose Structure-Function Correlation

Sarepta relies upon a single purported "structure-function correlation." D.I. 469 at 9. According to Sarepta, AO candidates ostensibly "induce exon 53 skipping" because their "structural features collectively target the claimed ASOs to [a] exon 53 hot spot" that spans "positions 23 to 69" on dystrophin pre-mRNA. *See id.* at 2-4, 7. This argument necessarily fails.

a. Sarepta Improperly Seeks to Revive the "Newly Characterized Antigen" Exception

Sarepta's argument is materially indistinguishable from the "newly characterized antigen"

test rejected by the Federal Circuit. That test "allow[ed] patentees to claim antibodies by describing . . . the antigen" to which the antibodies bound. *Amgen Inc. v. Sanofi*, 872 F.3d 1367, 1378 (Fed. Cir. 2017). Here, Sarepta argues for written description based on the region to which the AO candidates bind—the purported "hot spot"— even though the specification makes no mention of a "hot spot" or any defined region ranging from positions +23 to +69, (D.I. 401 (SOF) ¶ 3).[5] As the Federal Circuit explained, this approach "flouts basic legal principles of the written description requirement." *Id.* "Section 112 requires a 'written description of the invention,'" but this antigen/binding site approach allows patentees to "describ[e] something that is not the invention." *Id.* Although Sarepta claims that targeting this "hot spot" provides a structural feature shared by all claimed AOs, that is not true. As detailed in NS's Opening Brief, (D.I. 400), candidate AOs may satisfy all structural claim requirements while having entirely different, non-overlapping "12 consecutive bases of SEQ ID NO: 195." *Id.* at 12.

Sarepta's authority reinforces that no "common" structural features exist. In *UroPep*, the patentee did not merely show that all claimed PDE5 inhibitors "fit[] into the active site of the PDE5 enzyme." *Erfindergemeinschaft UroPep GbR v. Eli Lilly & Co.*, 276 F. Supp. 3d 629, 653 (E.D. Tex. 2017). It established that each PDE5 inhibitor shared a common "physical structure resembl[ing] an envelope" enabling that fit. *Id.* And in *Ajinomoto*, a POSA could "make relatively predictable changes" to disclosed promoters by modifying them towards a shared "consensus sequence." *Ajinomoto Co. v. Int'l Trade Comm'n*, 932 F.3d 1342, 1359-61 (Fed. Cir. 2019).[6]

[5] The different field of art provides no basis to adopt an exception here. The Federal Circuit "generally eschew[s] judicial exceptions to the written description requirement based on the subject matter of the claims." *Id.* at 1379. And the art is highly unpredictable. *Supra* Section I.B.

[6] Additionally, neither case supports Sarepta because each considered inventions from fields of art that were well-established (and thus predictable) before their filing date. *Erfindergemeinschaft UroPep*, 276 F. Supp. 3d at 650; *Ajinomoto*, 932 F.3d at 1359. Here, even Sarepta argues that the state of the art was lacking. D.I. 470 (CSOF) ¶ 1.1; D.I. 401 (SOF) ¶ 13; *supra* Section I.B.

b. The Specification Fails to Distinguish Functional and Non-Functional AO Candidates

Sarepta's argument is also diametrically opposed to another foundational principle of written description—that the "specification must demonstrate that the applicant has made a generic invention that achieves the claimed result." *AbbVie Deutschland GmbH & Co., KG v. Janssen Biotech, Inc.*, 759 F.3d 1285, 1299 (Fed. Cir. 2014). The specification nowhere teaches what structures distinguish functional AO candidates targeted to the purported "hot spot" from nonfunctional AO candidates targeted thereto. D.I. 401 (SOF) ¶¶ 2-3. Sarepta does not allege otherwise. It instead argues that a POSA would have "understood" the supposed correlation because she would generally seek AOs with an undefined "sufficient degree of complementarity or precise pairing." D.I. 469 at 10 (citing *id.* at 3-5, 7-8).

This is merely a "wish or plan for obtaining the claimed invention." *Juno Therapeutics, Inc. v. Kite Pharma, Inc.*, 10 F.4th 1330, 1335 (Fed. Cir. 2021). Sarepta's purported structural limitations "draw[] a fence around the outer limits of a purported genus" corresponding to the hot spot, *see Ariad Pharm. Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1350 (Fed. Cir. 2010) (en banc), and the specification tells POSAs that they should seek out a sufficient degree of complementarity or precise pairing. But the specification leaves it entirely to POSAs to determine within that hot spot what structural features are actually "sufficient" to induce exon skipping, even though "operative sequences are actually highly unpredictable, varying with parameters such as nucleobase sequence" and "length." D.I. 401 (SOF) ¶ 13.

The Federal Circuit's recent *PureCircle* decision—which Sarepta ignores—expressly rejected this approach. Just as Sarepta suggests a POSA would prioritize complementarity to the "hot spot" to narrow AO candidates, the patentee in *PureCircle* argued that a POSA would prioritize "homology modeling" to narrow enzyme candidates. *PureCircle*, 2024 WL 20567, at

*3. Whereas Dr. Dowdy's best efforts only narrow AO candidates to hundreds of thousands, (*supra* Section I.A), the *PureCircle* patentee's argument narrowed enzyme candidates to as few as 9,000, (2024 WL 20567, at *3). Even with that smaller candidate pool, the Federal Circuit found that trial-and-error experimentation "to identify potential active candidates" would be "extensive," and affirmed summary judgment of no written description. *Id.* It explained: "The question before us is not whether one of ordinary skill in the art presented with the [relevant] application would have been enabled to take those final steps, but whether the [relevant] application 'discloses the [variants] to him, specifically, as something appellants actually invented." *Id.* (quoting *Novozymes A/S v. DuPont Nutrition Biosciences APS*, 723 F.3d 1336, 1350 (Fed. Cir. 2013)).

Sarepta's attempt to distinguish *Idenix* is also misplaced. Knowing that an AO must "be highly complementary to a limited region of the dystrophin pre-mRNA within the known sequence of exon 53," (*see* D.I. 469 at 12-13), leaves a POSA with many thousands of candidates, (*supra* Section I.A), most of which have mismatches and high functional unpredictability, (*supra* Section I.B). The specification in *Idenix* similarly established "tens or hundreds of thousands of possible nucleosides, substituent-by-substituent," but still lacked sufficient written description because its "lists or examples of supposedly effective nucleosides" did "not explain what makes them effective, or why." 941 F.3d at 1164-65. Sarepta's attempt to distinguish *Juno* fares no differently. Just as the patentee in *Juno* could not rely upon the "general common structure" of scFvs because "a different amino acid sequence would [cause the scFv to] recognize a different antigen," 10 F.4th at 1339, Sarepta cannot rely upon the general common structure of morpholino AOs because differing base sequences may cause the AOs to induce or not induce exon 53 skipping.

c. Sarepta Improperly Relies Upon Post-Priority Date Evidence

Left with the specification's failure to identify structural differences between functional and non-functional candidates, Sarepta resorts to arguing that a POSA would know that "most, if

not all, of these [candidate] ASOs" having the claimed "structural features" would induce exon skipping based on post-patent experimentation. D.I. 469 at 2, 8, 16. As support, Sarepta cites purported "real-word examples" that supposedly "validat[e] the structure-function correlation." D.I. 469 at 17. Even if this post-priority date evidence did so, it would not help Sarepta. The specification must convey "possession of the claimed subject matter as of the filing date." *Ariad*, 598 at 1351. No amount of post-priority date evidence can substitute for the UWA Patents' lacking disclosure. *Amgen*, 872 F.3d at 1374.

Regardless, Dr. Dowdy's post-priority date examples do not establish any structure-function correlation common across the claimed genus. Each "example" is 100% complementary to the dystrophin pre-mRNA. D.I. 427-2, Ex. 2 (Dowdy Rebuttal) at ¶ 79, tbls. 3, 4 (Popplewell and Sazani AOs from 2010), ¶ 82, tbls. 5, 6 (NS testing from 2011 application), ¶ 84, tbls. 7, 8 (Sarepta AOs), ¶ 85, tbls. 9, 10 (Sarepta testing from 2014 application), ¶ 86, tbls. 11, 12 (other Sarepta testing), ¶ 88, tbls. 13, 14 (other NS testing); ¶¶ 89-91, tbls. 15, 16 (UWA testing of non-morpholinos). Dr. Dowdy provides no examples with 1, 2, 3, or 4 mismatches or insertions, which account for most of the claimed genus.[7] Thus, as in *AbbVie*, this evidence cannot establish structure-function correlation over the full breadth of the genus. 759 F.3d at 1300 (antibodies "all of the similar type" did "not qualitatively represent other types" claimed).

Thus, no reasonable jury could find that the specification discloses a structure-function correlation common across the genus.

2. The Specification's Sole "Species" Is Not Representative

Sarepta briefly addresses NS's argument regarding "representative species," noting only

[7] Sarepta critiques Dr. Hastings's testing of AOs with various non-complementary sequences. D.I. 469 at 16. But she actually undertook what Dr. Dowdy failed to do: assess the likelihood of exon skipping functionality across the **entire** breadth of the claim. *See* D.I. 400 at 14-15.

the lack of "bright-line rules" and contesting a demonstrative figure. D.I. 469 at 17-18. Sarepta's failure to meaningfully address NS's argument demonstrates that it cannot prevail on this prong.

NS's Opening Brief made clear why SEQ ID NO: 195 alone is not representative. D.I. 400 at 6-11. Where "the art is unpredictable . . . disclosure of more species is necessary." *Synthes USA, LLC v. Spinal Kinectics, Inc.*, 734 F.3d 1332, 1344 (Fed. Cir. 2013). Likewise, "relatively few representative examples" do not suffice where "tens or hundreds of thousands of possible" structural candidates exist, and yet "the [accused product] is conspicuously absent." *Idenix*, 941 F.3d at 1165. Both are the case here. *Supra* Sections I.A-B; D.I. 400 at 6-11. The disclosed species must be "representative of the full variety or scope of the genus." *PureCircle*, 2024 WL 20567, at *4 (quoting *AbbVie*, 759 F.3d at 1300). But here, as in *PureCircle*, "the one [AO] disclosed in the patents here has not been shown to be typical of the entire genus [] claimed." *Id.* Summary judgment of no written description is therefore appropriate.

D. The UWA Patents Are Invalid For Lack of Enablement

Sarepta also opposes NS's motion for summary judgment of non-enablement, arguing that (1) NS failed to establish "that any experimentation is necessary," (D.I. 469 at 19); (2) any experimentation was "routine," (*id.* at 19-22); and (3) the claims' recited "structural features" set them apart, (*id.* at 22-23). None of these arguments hold water.

1. The Art's Unpredictability Establishes a Need for Experimentation

NS's Opening Brief detailed evidence showing the need for trial-and-error experimentation. *See* D.I. 400 at 16-18. Sarepta itself asserts that the art was highly unpredictable before the UWA Patents' filing. *See* D.I. 470 (CSOF) ¶ 1.1. And there is no genuine dispute that the art continued to be highly unpredictable after June 2005. *Supra* Section I.B.

Sarepta's statements in the '007 Interference are telling. On November 18, 2014, it stated:

Exon skipping of dystrophin pre-mRNA was a nascent and highly unpredictable

> technology as of the time of the invention (and remains so today).

D.I. 427-23, Ex. 23 (UWA Mot. 1) at 17. It further argued:

> [T]here is tremendous variability and unpredictability in the efficacy of different AONs targeted to different regions of the dystrophin pre-mRNA, and each different AON needs to be empirically.

Id. at 4; *see also* D.I. 401 (SOF) ¶¶ 12, 15 ("[T]he need to test each and every AON is also reflected in UWA's specification."). Sarepta cannot distance itself from representations it made to the PTO explicitly advocating the need for individualized testing.

Sarepta's opposition thus again resorts to post-priority date evidence that legally and logically fails. D.I. 469 at 19. The law does not permit patentees to cure non-enablement using post-priority date evidence of the state of the art. *Amgen*, 872 F.3d at 1374-75 (*In re Hogan* involved enablement and prohibits "post-priority-date evidence proffered to illuminate the post-priority-date state of the art") (citing *In re Hogan*, 559 F.2d 595 (CCPA 1977)). It only allows post-priority date evidence *to show* non-enablement through POSAs engaging in "lengthy and potentially undue experimentation" after the priority date. *Id.* at 1375. Taken in that light, Dr. Dowdy's evidence of extensive post-priority experimentation weighs against enablement.

Even if accepted, the cited evidence at best suggests that a POSA having the opportunity to examine another decade's worth of later generated data might expect less unpredictability regarding the small portion of the genus having 100% complementary AOs. *See supra* Section I.C.1.c. That (disputed) fact is immaterial to the enablement standard, which is evaluated based on what "the specification teach[es]," what is known "at the effective filing date," and requires enablement of the claims' "full scope." *Idenix*, 941 F.3d at 1154.

2. Any Disputes Identified by Sarepta Are Not "Material"

Sarepta next points to purported disputes regarding various *Wands* factors. Sarepta cites the relative skill of POSAs and methods for making and testing AOs, (D.I. 469 at 19-20), the

specification's guidance, (*id.* at 20-21), the level of unpredictability, (*id.* at 21-22), and whether experimentation would be "routine," *(id.* at 22). None of these merit denying summary judgment.

Starting with unpredictability, Sarepta is wrong for the reasons discussed above. *Supra* Sections I.B, I.D.1. With respect to "the level of skill in the art" and "routine" nature of synthesis and screening, *Idenix* and *Wyeth* illustrate why Sarepta's remaining contentions fail to establish any "material" factual disputes. In *Idenix*, the Federal Circuit assumed that "the level of ordinary skill in the art is high," that "synthesis of an individual nucleoside was largely routine," and that "that screening an individual compound for effectiveness was considered 'routine.'" 941 F.3d at 1156, 1160, 1163. The same is true in *Wyeth*. *Id.* at 1162-63 (discussing *Wyeth & Cordis Corp. v. Abbott Lab'ys*, 720 F.3d 1380 (Fed. Cir. 2013)). Yet, in both cases, the Federal Circuit still found "undue experimentation" because "[a] reasonable jury could only have concluded that there were at least many, many thousands of candidate compounds, many of which would require synthesis and each of which would require screening." *Id.* at 1163. That is precisely what is required here. The candidate AOs undisputedly number at least in the tens or hundreds of thousands (if not hundreds of trillions), (*supra* Section I.A), and screening is required to assess each's functionality, (*supra* Sections I.B, I.D.1). [redacted] parallels key admissions in *Idenix* and *Wyeth*.[8]

Idenix also makes clear the flaw in Sarepta's "hot spot" theory. Even if the UWA Patents direct POSAs to "target" highly complementary AOs to positions +23 to +69, they would still fail to provide an enabling disclosure. "It is not enough to identify a 'target' to be the subject of future

[8] *Idenix*, 941 F.3d at 1163 (a "Wyeth scientist" testified that "until you test [compounds], you can't really tell whether they work or not" and an "Idenix scientist" that "you don't know whether or not a nucleoside will have activity against HCV until you make it and test it.").

testing." *Idenix*, 941 F.3d at 1161. "A specification that requires a POSA to 'engage in an iterative, trial-and-error process to practice the claimed invention' does not provide an enabling disclosure." *Id.* (quoting *ALZA Corp. v. Andrx Pharm.*, LLC, 603 F.3d 935, 941 (Fed. Cir. 2010)).

3. The Claims' Structural Features Do Not Distinguish this Case

Sarepta last tries to distinguish *Amgen*, *Baxalta*, *Idenix*, and *Wyeth*, arguing that the existence of "structural features" that aid a POSA in "arriv[ing] at compounds having the claimed function." D.I. 469 at 22-23. Sarepta's arguments fail for three reasons.

First, Sarepta is wrong that its purported structural limitations matter. They do not obviate the Supreme Court's mandate that "the more a party claims, the broader the monopoly it demands, the more it must enable." *Amgen, Inc. v. Sanofi*, 598 U.S. 594, 610 (2023). By limiting the claims to particular exon 53-skipping AOs, rather than claiming all exon 53-skipping AOs, Sarepta has undoubtedly laid claim to a smaller (yet still vast) genus than it might have. Although Sarepta may not have to enable every AO that induces exon 53 skipping, it must still enable each functional AO within the numerous candidates the UWA Patents do encompass. Sarepta chose to cast its claims far beyond the four exemplary AOs ostensibly establishing the purported "hot spot." The claims permit variability along parameters such as a candidate's length (20 to 31 bases), target site within the "hot spot," base sequence, and complementarity. This leads to highly unpredictable functionality, particularly when mismatches are present. D.I. 401 (SOF) ¶¶ 12-15. "[T]he specification must enable th[is] full scope of the invention," not just a portion of it. *Amgen*, 598 U.S. at 610. And that is precisely what the specification fails to do.

Second, Sarepta is wrong to try to distinguish these cases factually based on purported "differences in technology." *See* D.I. 469 at 23-24. Whether antibodies, nucleosides, or antisense oligonucleotides, each field of art is highly unpredictable. *Compare supra* Section I.B, *with Idenix*, 941 F.3d at 1161 (noting testimony that field was previously "nascent" and that "you don't know

whether or not a nucleoside will have activity against HCV until you make it and test it").

Third, Sarepta's reliance on the hot spot "target sequence" runs headlong into the Supreme Court's lock-and-tumbler analogy. Even if a POSA used that pre-mRNA sequence to derive the numerous possible candidate AOs, that is no different than a POSA deriving possible combinations for a "combination lock with 100 tumblers, each of which can be set to 20 different positions." *See Amgen*, 598 U.S. at 614. This type of "'roadmap' would produce functional combinations," "[b]ut it would not enable others to make and use functional combinations." *Id.* at 615.

A reasonable jury could only find that making and using the full scope of the claimed genus requires making and screening at least many thousands of candidates. The experimentation required is therefore undue, and the Court should find the UWA Patents non-enabled.

II. THE COURT SHOULD GRANT JUDGMENT THAT SAREPTA INFRINGES THE NS PATENTS

Sarepta's only response to NS's motion for summary judgment of infringement is that Sarepta's dismissal of its noninfringement defenses renders the motion moot. D.I. 469 at 24. Not so. Even absent a defense, NS still bears the burden to prove infringement. *Novartis Corp. v. Ben Venue Labs., Inc.*, 271 F.3d 1043, 1046 (Fed. Cir. 2001). As Sarepta identifies no disputed fact in its response, (D.I. 469 at 24), NS has met that burden, and summary judgment should be granted.

III. THE COURT SHOULD GRANT JUDGMENT OF BREACH OF CONTRACT

Sarepta's belated efforts to manufacture factual disputes cannot defeat NS's motion for summary judgment of breach of contract. Sarepta's retorts and attorney argument do not change three fundamental, undisputed facts: (1) Sarepta breached the MCA; (2) Sarepta's damages expert, Mr. Jarosz, proffered $[redacted] as the appropriate damages figure; and (3) Sarepta presents no evidence challenging the reasonableness of NS's attorneys' fees. These facts entitle NS to summary judgment and an award of $[redacted] in damages for Sarepta's breach of contract.

A. There Is No Material Dispute of Fact Regarding Sarepta's Breach of the

MCA and NS's Substantial Compliance with the MCA.

Sarepta does not substantively dispute the facts of its breach or that the Federal Circuit's ruling is law of the case. *See* D.I. 406. Sarepta thus concedes that it breached the MCA. Despite this, Sarepta tries to avoid summary judgment by arguing that NS's purported own breach of the MCA limits its remedy because NS supposedly has not substantially complied with the MCA. *See* D.I. 469 (Opp'n) at 27-28. Sarepta's argument fails as a matter of law.

Under the substantial compliance doctrine, a "technical breach of the terms of a contract is excused" where it "is immaterial." *See* 15 Williston on Contracts § 44:52 (4th ed. 2008). The undisputed record evidence demonstrates that NS's supposed breach was, at most, an immaterial, technical breach. Indeed, Judge Stark's ruling striking the paragraphs of now-superseded complaints that allegedly violated the MCA forecloses any finding of materiality. *Cf. Norfolk S. Railway Co. v. Basell USA Inc.*, 512 F.3d 86, 92 (3d Cir. 2008) (setting forth Restatement (Second) of Contract factors when assessing materiality under Delaware law). Sarepta cannot show (a) it was deprived of the benefits of the MCA (Judge Stark's ruling ensured it received them); (b) it cannot be adequately compensated for a breach (Judge Stark's ruling avoided any damage); (c) that there was any forfeiture or risk thereof (there was none); (d) that there is not a likelihood of cure (Judge Stark's ruling already cured any breach); or (e) that NS acted with anything less than good faith (NS's good faith arguments regarding its contract interpretation, (*see* D.I. 44 at 4-9)). Sarepta also offers no evidence of non-remediated harm flowing from NS's actions.

Because the record lacks any evidence that NS's inclusion of confidential information in now-obsolete complaints "materially" breached the MCA, there is no factual dispute surrounding NS's substantial compliance. Thus, the Court should determine that, as a matter of law, NS did not materially breach the MCA and is therefore not barred from recovery for Sarepta's breach. *See Norfolk*, 512 F.3d at 93 ("[I]t can be appropriate to determine the issue of material breach at the

summary judgment stage."); *Paul v. Deloitte & Touche, LLP*, 974 A.2d 140, 144 (Del. 2009) (affirming summary judgment); *Certain Underwriters at Lloyds, London v. McDermott Int'l, Inc.*, No. CIV.A. 01-912, 2002 WL 22023, at *5 (E.D. La. Jan 4. 2022) (determining non-materiality at summary judgment phase because "record is clear that confidentiality was not the *sine qua non*" of agreement at issue).[9] Because NS undisputedly substantially performed its obligations under the MCA, the Court should grant judgment on Sarepta's liability for breach of the MCA.

B. There Is No Genuine Dispute Regarding the Amount of NS's Damages.

Sarepta also seeks to manufacture a dispute over damages. Although Sarepta disputes that its damages expert opined the appropriate measure of damages for NS's breach of contract claim was $[redacted] the record is undisputed. The sole document Sarepta cites to refute NS's statements regarding its damages expert's total calculation of breach of contract damages is Mr. Jarosz's Report, (D.I. 469 at 26-27; Sarepta's RSOF 3.1)—which lists that total damages for NS's breach of contract claim are $[redacted], (Ex. 10, ¶¶ 198, 320). Sarepta now claims Mr. Jarosz offered a "range" for damages, (D.I. 469 at 24, 26), but Sarepta's assertion is belied by the single total breach of contract damages figure set forth in Mr. Jarosz's Report. *See* Ex. 10, ¶¶ 198, 320.

Sarepta's efforts to belatedly rewrite its damages expert report cannot preclude summary judgment. Sarepta states that it intends to argue at trial that damages are "much lower" than the figure its damages expert offered. D.I. 469 at 26. But Mr. Jarosz will be limited to the opinions expressed in his report—opinions that do not include an undefined "far less" (and undisclosed)

[9] Because any technical breach by NS was immaterial, the cases Sarepta cites involving material breaches are inapposite. *See MD Helicopters Inc. v. Boeing Co.*, No. CV-17-02598-PHX-JAT, 2019 WL 3840974, at *11 (D. Ariz. Aug. 15, 2019) (allegations of material breach for contract that required "strict compliance" were sufficient to raise factual question precluding summary judgment); *Edelstein v. Goldstein*, C.A. No. 09C-05-034 DCS, 2011 WL 721490, at *5 (Del. Super. Mar. 1, 2011) (record of evidence of material breach by party seeking to enforce contract was sufficient to raise factual question precluding summary judgment).

damages number. *See Honeywell Int'l, Inc. v. Univ. Avionics Sys., Corp.*, 289 F. Supp. 2d 493, 500 (D. Del. 2003) (declining to consider undisclosed opinions at summary judgment phase because "the testimony of expert witnesses is limited to . . . in their expert reports"). Thus, Sarepta's undisclosed supposedly "[redacted]" damages number cannot create a genuine factual dispute.

Likewise, Sarepta's belated complaints regarding the reasonableness of NS's fees cannot preclude summary judgment. Sarepta misleadingly asserts that "Mr. Jarosz has raised the [ ] issue of reasonableness of legal fees incurred by NS." D.I. 469 at 27. Mr. Jarosz never raised this issue as to the fees included in his $[redacted]amages figure, and the Court need look no further than the paragraphs Sarepta cites of Mr. Jarosz's Report. *Id.* (citing Ex. 10, ¶¶ 194-98). In those paragraphs, Mr. Jarosz critiques other billing entries (from before Sarepta filed its IPR Petitions), (Ex. 10, ¶ 195), as relating to tasks that appeared unrelated to the IPRs or breach of the MCA, (*id.*, ¶ 196). Mr. Jarosz accordingly omitted these fees from his damages calculation and did not otherwise offer opinions regarding the reasonableness of the fees from which he calculated his $[redacted] damages figure. *See id.*, ¶¶ 195-198. Mr. Jarosz's ultimate figure likewise applied a [redacted] he claimed was missing. *Id.* ¶ 197.

The other two cited paragraphs pertain (1) to NS's damages expert (Mr. Hosfeld) [redacted] based on these factors and others in paragraphs 195-197, (*id.*, ¶ 198), and (2) a summary of Mr. Hosfeld's opinions, (*id.*, ¶ 194). Nowhere in the paragraphs Sarepta's Opposition cites nor Mr. Jarosz's Report is there any assertion—let alone opinion—that NS's attorneys' fees are unreasonable. Thus, Sarepta's cited authority regarding reasonableness of fees is inapposite. *See Nissan N. Am. Inc. v. Schrader Elecs., Ltd.*, No. 3:13-CV-180, 2014 WL 5410296, at *11 (M.D. Tenn. Oct. 23, 2014) (noting "dueling expert reports" on reasonableness

of fees).[10] Sarepta cannot create a genuine dispute of material fact by suggesting its expert will belatedly offer new opinions at trial. *See Honeywell*, 289 F. Supp.2d at 500 (D. Del. 2003); *cf. Cuffee v. Dover Wipes Co.*, 334 F. Supp. 2d 565, 572 (D. Del. 2004) (excluding expert testimony on damages where no report on issue was timely submitted); *Moore N.A., Inc. v. Poser Business Forms, Inc.*, No. Civ.A. 97-712-SLR, 2001 WL 253117, at *7 (D. Del. Mar. 8, 2001) (precluding enablement defense not covered in expert report); *Arthrocare Corp. v. Smith & Nephew, Inc.*, No. Civ.A. 01-504-SLR, 2003 WL 1905636, at *1 (D. Del. April 14, 2003) (excluding certain expert testimony that went beyond scope of expert report because "experts are limited by their reports").

At bottom, NS has stipulated to the very breach of contract damages figure Sarepta's expert proffered. Sarepta cannot avoid judgment by attempting to offer undisclosed damages calculations.

IV. THE COURT SHOULD GRANT JUDGMENT OF NO ANTICIPATION

It is undisputed that '212 Popplewell **does not expressly** disclose the 5'-TEG limitation. D.I. 469 (Opp'n) at 31 ("Popplewell '212 does not 'expressly' refer to the 5'-TEG modification."). Sarepta's expert, Dr. Dowdy, nevertheless opined that '212 Popplewell anticipates the 5'-TEG claims because "a POSA as of August 31, 2011 would **at once envisage** the TEG modification." D.I. 410 (Mot.) at 1. The Federal Circuit, however, has made clear that the "at once envisage" test "does not permit . . . fill[ing] in missing limitations" simply because a POSA can envisage them. *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co. Ltd.*, 851 F.3d 1270, 1274-75 (Fed. Cir. 2017). Thus, Sarepta's anticipation argument fails as a matter of law.[11]

[10] Likewise, Sarepta's citation to *Precision Indus. v. Behnke Lubricants, Inc.*, 396 F. Supp. 2d 1012, 1019 (S.D. Iowa 2005) is misplaced. That case involved a lack of evidence regarding whether one party had paid arguably outstanding debts, and, thus, is inapposite. *See id.* at 1019. Here, there is no dispute that Sarepta has not paid NS's legal fees.

[11] Sarepta argues that *Nidec* and related cases "are inapposite because they all involve situations where a limitation is entirely missing from the asserted prior art reference [whereas] [h]ere, a POSA would know that exon-skipping PMOs have a 5' end." D.I. 469 (Opp'n) at 31. But the undisputed fact remains that the "**TEG**" limitation is "**entirely missing**" from '212 Popplewell.

Sarepta responds that it is not "using the knowledge of a POSA to fill in a limitation that is missing from '212 Popplewell" but rather relying on what "a POSA would reasonably understand and infer" from '212 Popplewell. D.I. 469 (Opp'n) at 30. However, Sarepta's new-found wording makes no difference—'212 Popplewell still fails to disclose the TEG medication and is not anticipatory. The cases on which Sarepta relies—*Acoustic Technology*, *VirnetX* and *Baxter*—are irrelevant. Those cases make clear that the "reasonably understand or infer" standard relates to *inherent anticipation*, a theory that Sarepta never advanced until now. D.I. 410 (Mot.) at 2, n.1. Even if considered, however, Sarepta's new inherent anticipation theory fails.

In *Acoustic Technology*, the Court found anticipation only after relying on expert testimony that the prior art's disclosure of "radio wave communication was **the same as** [the claimed limitation]." *Acoustic Tech., Inc. v. Itron Networked Sols., Inc.*, 949 F.3d 1366, 1373 (Fed. Cir. 2020). Likewise, in *VirnetX*, the Court found that a POSA "would have immediately understood" that an "authentication failure" in the prior art system "**would result in** [the claimed limitation]." *VirnetX Inc. v. Apple Inc.*, 2023 WL 6933812, at *4 (Fed. Cir. Oct. 20, 2023) (the Court further noting that "[t]he core inquiry is whether a person of ordinary skill in the art would understand the reference to **disclose the limitation** in question, **rather than merely 'envisage' a limitation** that is in fact missing from the reference."). And in *Baxter*, the prior art referred to Baxter's commercial systems, and it was **undisputed** that "Baxter's commercial systems during this time period **all** contained a primary bag plasticized with DEHP." *In re Baxter Travenol Labs.*, 952 F.2d 388, 390 (Fed. Cir. 1991). Thus, the Court found that a POSA would have known that the disclosed bag was ***necessarily*** plasticized with DEHP. *Id.*

Here, in contrast, Sarepta merely argues that 5'-TEG was a "prominent choice (out of only three) for that end," (D.I. 469 (Opp'n) at 31)—not that **all** PMOs at the relevant time contained a

5'-TEG modification. *See also id.* ("a POSA would understand the disclosure of the relevant 'PMO' in Popplewell '212 to include a 5'-TEG as one of three possible choices for exon-skipping PMOs."); *id.* at 30 ("A POSA at the time would also 'at once envisage' 5'-TEG as one of only three choices of 5'-end group (along with an amide group and a hydroxyl group) for exon-skipping PMOs."). Because Sarepta has failed to present any evidence that the PMOs of '212 Popplewell **necessarily** have a 5'-TEG, Sarepta's new argument for inherent anticipation fails. *Akamai Techs., Inc. v. Cable & Wireless Internet Servs., Inc.*, 344 F.3d 1186, 1192 (Fed. Cir. 2003) ("A claim limitation is inherent in the prior art [only] if it is necessarily present in the prior art, **not merely probably or possibly present**.").[12]

The Court should grant NS's motion for judgment of no anticipation for the 5'-TEG claims.

V. THE COURT SHOULD GRANT JUDGMENT OF NO INEQUITABLE CONDUCT

Sarepta spills much ink on intent to deceive. *See* D.I. 469 at 33-35. But this Court need not decide whether a specific intent to deceive is a reasonable inference, much less the single most reasonable inference, that could be drawn from the unremarkable facts that [redacted] D.I. 469 at 33-34; *see also* D.I. 328 at ¶¶ 219-225. Rather, the Court can and should grant summary judgment of no inequitable conduct to NS based on the lack of but-for materiality of the allegedly withheld data and reference.

Allegedly withheld data. The inescapable conclusion from the undisputed facts is that the allegedly withheld data is cumulative to the contents of the NS Patents' specification. Sarepta

[12] Sarepta's reliance on *Genentech* and *Gleave* is similarly misplaced. In *Genentech*, the Court found that a single "Example 1" in the prior art reference ***expressly disclosed*** every claim limitation. *Genentech v. Hospira*, 946 F.3d 1333, 1337-40 (Fed. Cir. 2020). Likewise, in *Gleave*, the single prior art reference "***expressly list[ed] every possible*** fifteen-base-long oligodeoxynucleotide sequence in IGFBP–2." *In re Gleave*, 560 F.3d 1331, 1338 (Fed. Cir. 2009).

argues that the allegedly withheld data demonstrates "the claimed ASO showed ***inferior*** skipping to Popplewell '212 ASOs" and "completely undermined" NS's argument of unexpected superiority. D.I. 469 at 36. But Sarepta's response and Dr. Dowdy's testimony confirm that the specification already included data undermining NS's argument of unexpected superiority (assuming for summary judgment only that the claims were allowed due to that argument).

Per Sarepta, "Dr. Dowdy explained that figures 16 and 17 showed 'comparable' exon skipping between the claimed ASO and a prior art ASO…" D.I. 470, Sarepta Response to SOF ¶ 10 (citing D.I. 427-13, Dr. Dowdy's deposition); D.I. 427-1 (Dowdy Opening) ¶¶ 646-647. Dr. Dowdy confirmed at deposition that Figures 16 and 17 showed the claimed ASO did not have superior skipping activity to the prior art ASOs, testifying that they were either "almost identical" or the claimed ASO was "slightly worse." Ex. 60, Dowdy Dep. at 141:18-142:13; *see also* D.I. 472-1 (Dowdy Opening) ¶ 648. "Comparable" or "almost identical" activity is ***not*** superior activity, as plainly shown in Figs. 16 and 17. *See* Ex. A (comparing annotated Figs. 16 and 17 with Dr. Dowdy's annotated Figs. 16 and 17 from his Opening Report).

Because Dr. Dowdy affirmatively opined and confirmed at deposition, the head-to-head data in Figures 16 and 17 indicates that NS's claimed ASO did not have superior skipping activity, the same as what the allegedly withheld data shows (D.I. 472-1, Dowdy Opening ¶ 648; Ex. 60, Dowdy Dep. at 148:13-18) the allegedly withheld data is cumulative and not but-for material to patentability as a matter of law.[13] *See Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd.,* 719 F.3d 1346, 1358 (Fed. Cir. 2013) (finding no but-for materiality where declaration disclosed results that allowed the examiner the opportunity to weigh the inventor's and prosecuting attorney's assertions

[13] NS argued the allegedly withheld data was cumulative. D.I. 415 at 3 ("[t]hus, omitted data points were cumulative to information showing a lack of superiority that was before the examiner").

and arguments); *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.,* 537 F.3d 1357, 1371 (2008) (reversing finding of materiality because the specification and reference disclosed to PTO contained the same "critical information" as the withheld references).

Sazani 2010. The "additional disclosures" of Sazani 2010, which Sarepta identifies as genotoxicity and pharmacology safety studies, (D.I. 469 at 36), cannot be material to patentability of the ***claims*** as a matter of law because the ***claims*** have no such limitations. *Regeneron Pharms., Inc. v. Merus N.V.,* 864 F.3d 1343, 1351 (Fed. Cir. 2017) ("the first step in determining but-for materiality of a reference is determining the scope of the claims at issue"); Ex. 60, Dowdy Dep. at 173:17-23 (agreeing that NS patent claims don't require safety or limitations relating to toxicity). As for relevant disclosures, Sazani 2010 discloses a PMO backbone with a 5'-TEG modification, which is undisputedly also disclosed in the Sazani '586, a reference provided to the PTO during prosecution. Ex. 60, Dowdy Dep. at 171:13-14 ("In Sazani '586… the pieces [of Sazani 2010] are there, but it's not all put together."). Sazani 2010 is therefore cumulative as a matter of law. *See Bausch Health Ireland Ltd. v. Padagis Israel Pharms. LTD*, 603 F.Supp.3d 107, 120 (D.N.J. 2022) (finding no materiality as a matter of law because "[a]t most, the [withheld reference] could have provided a shortcut to the Examiner's conclusion of obviousness, but it would not have changed that conclusion").

Sarepta cannot create a triable issue of fact by assuring this Court that Dr. Dowdy will testify to non-cumulativeness and materiality of Sazani 2010. As discussed in NS's *Daubert* motion, Dr. Dowdy is not qualified to render opinions regarding but-for materiality. Further, Sarepta must show there is a genuine dispute of material fact—it cannot do so by citing only to Dr. Dowdy's expert report while ignoring his admission at deposition that the disclosures of Sazani 2010 are found in Sazani '586. D.I. 469; Ex. 60, Dowdy Dep. at 171:13-14. Dr. Dowdy's

admissions render these facts undisputed and mandate a conclusion of no but-for materiality.

Finally, under Sarepta's anticipation argument, these claim limitations are also inherently disclosed in Popplewell '212 (a reference undisputedly considered by the examiner) and thus cumulative.[14] D.I. 469 at 30 ("a POSA would reasonably understand and infer that Popplewell '212 discloses the claimed PMO with a 5'-TEG modification"). Sarepta can be wrong twice, but cannot have it both ways. If Popplewell '212 anticipates, then Sazani 2010 cannot be but-for material, much less on the basis of the "additional disclosures" regarding PMO safety.

The Court should grant NS's motion for judgment of no inequitable conduct.

VI. CONCLUSION

NS respectfully requests that the Court grant its motions for summary judgment.

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Respectfully submitted,

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[14] Popplewell '212 also discloses that PMOs are safe. D.I. 416, NS Statement of Facts, ¶ 4.

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